CRT 21 Virtual

AorticLab Embrace Transcatheter Antiembolic Filter

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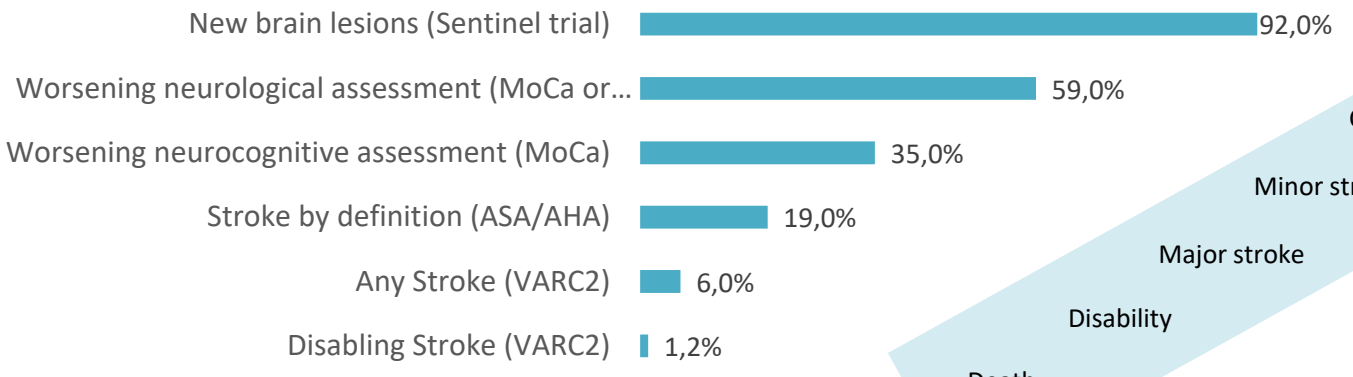
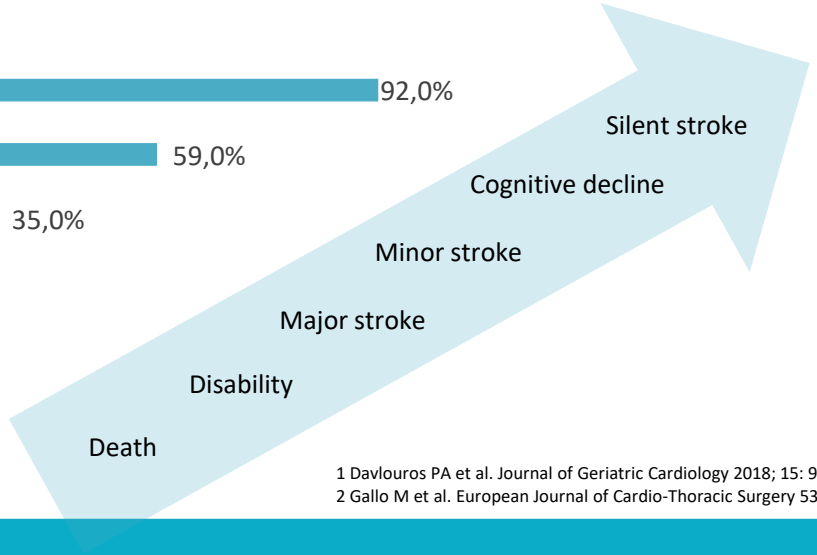
I have no relevant financial relationships

The TAVR procedure carries an inherent risk of stroke

Stroke is confined mainly in the periprocedural and 30-day period following TAVR and it is one of the most feared complications of TAVR because of its associated severe disability and high mortality[1]

During TAVR cerebrovascular accidents can occur at any time[2]



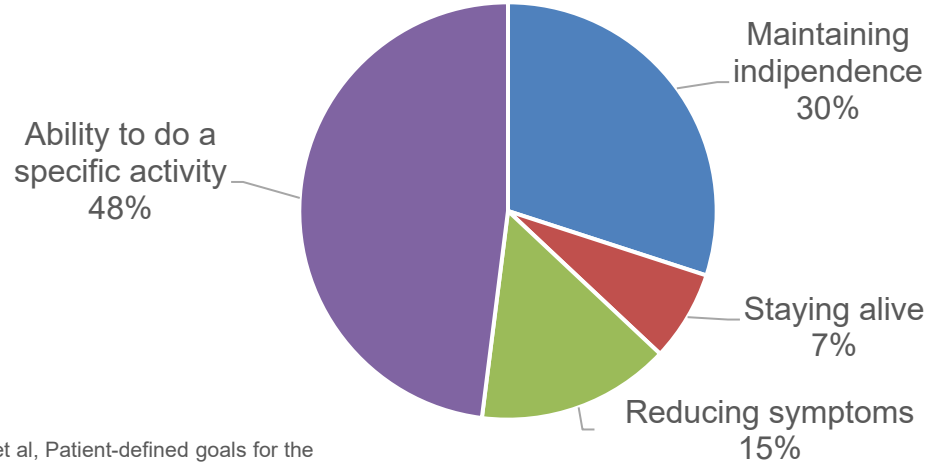


1 Davlouros PA et al. Journal of Geriatric Cardiology 2018; 15: 95-104;
2 Gallo M et al. European Journal of Cardio-Thoracic Surgery 53; 2018: 1118–26;

TAVI patients' goals

For TAVR patients is better to stay independent and active than alive.

Stroke is a major factor in these outcomes.



Source: Coylewright M., et al, Patient-defined goals for the treatment of severe aortic stenosis: a qualitative analysis

AorticLab solution

The transcatheter total body antiembolic system

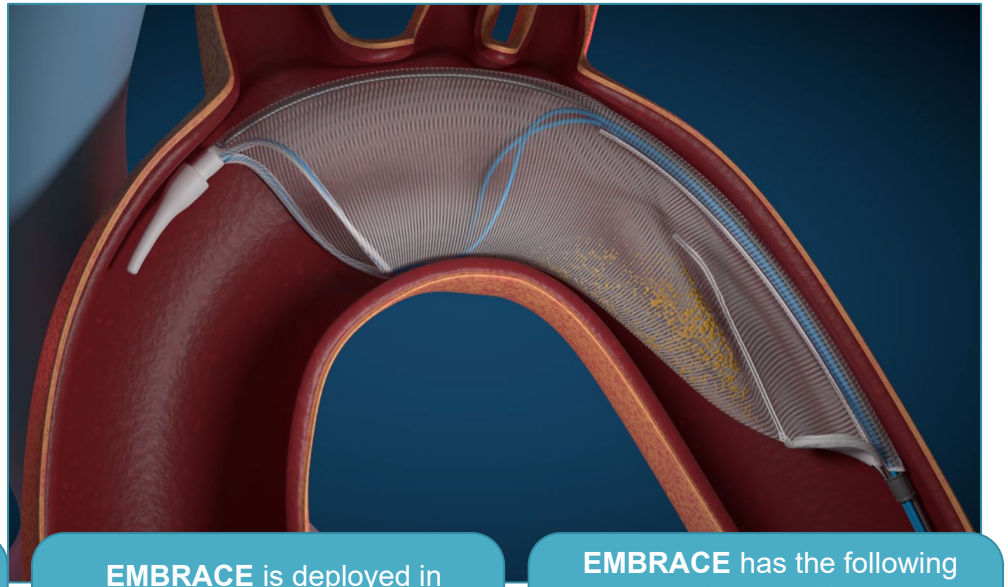

EMBRACE
WITH CATCH & FLOW TECHNOLOGY

EMBRACE – The transcatheter antiembolic filter

EMBRACE has been designed to protect cerebral and peripheral vessels

EMBRACE unique design is compatible with **ALL delivery systems**

EMBRACE will make TAVR procedures more safe in term of cerebral strokes, kidney and peripheral adverse events



Pigtail for TAVI procedures integrated in the **EMBRACE** delivery

EMBRACE is deployed in the ascending aorta in less than 5 minute and perfectly **fits with the aortic wall**

EMBRACE has the following unique quality:
≤ 70µm mesh pore
Compatibility with 12 Fr introducer for all sizes

EMBRACE In-Vitro test

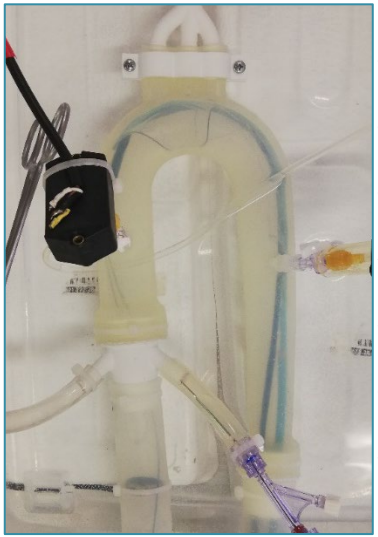
Debris capture ability test

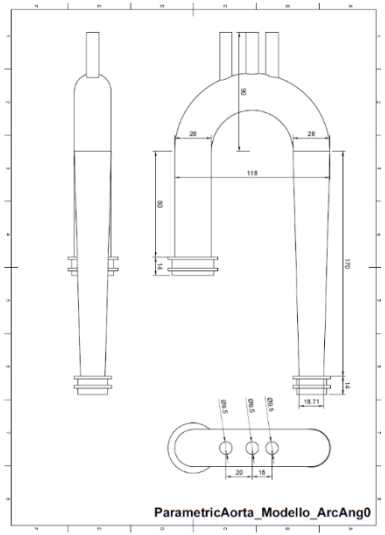
>150µm particles captured during
In-Vitro TAVI procedures

EMBRACE	Cerebral branches protection	Systemic protection
Mean±SD	99±1%	84±8%

Pressure drop

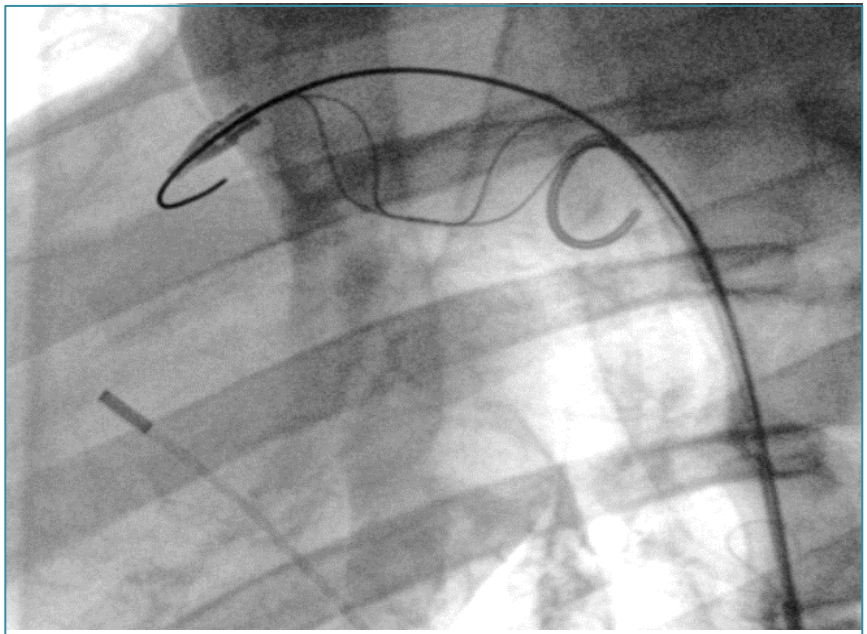
The Δp calculated through EMBRACE filter in the
In-Vitro test is **6.6 mmHg** @4,5 l/min cardiac output





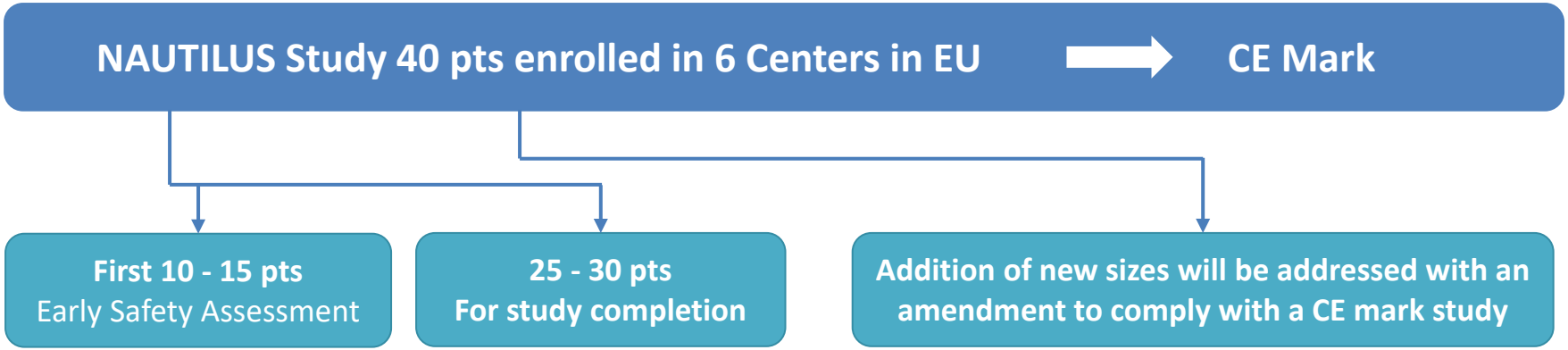
EMBRACE Usability test

Cardiologists perform EMBRACE In-Vivo test



EMBRACE In-Vivo test positioning

EMBRACE Clinical trial – Nautilus Study



Nautilus study endpoints

Performance Endpoints:	• **Technical Success** [Time Frame: immediately after procedure] defined as successful placement, insertion and removal of the EMBRACE System • **Debris capture** post-TAVI by the EMBRACE System with gross and histopathological evaluation including particle size and composition • **EMBRACE System Usability**, graded by the Investigator with a 5-point Likert scale
Clinical Benefit Endpoints:	• **Brain imaging (DW-MRI):** Acute cerebral embolic burden reduction after TAVI, defined as number and volume of new cerebral lesions in all cerebral territories assessed by DW-MRI [Timeframe: within 2-5 days after procedure vs. baseline]. • **Neurocognitive:** Neurocognitive protection assessed by NIHSS, Montreal Cognitive Assessment and mRS [Timeframe: 2-7 days and 30-days vs. baseline].

The essentials to remember

Stroke is one of the most feared complications of TAVI

Embolic protection devices act as a **mechanical barrier** to prevent emboli to reach cerebral vasculature

EMBRACE filter positioned in the aortic arch captures the debris released during the TAVI procedure with a dimension over 70µm

EMBRACE demonstrates to be quickly and easily deployed, compatible with different aortic arch geometries, stable during TAVI procedures and with a low thrombosis risk

Patients with lower risk profile and longer life expectancy, submitted to TAVI procedure, need to be protected from stroke